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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,961	05/17/2006	Christine Ambrose	08201.0039-00000	1436

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
05/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/550,961	AMBROSE ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,28-31,33-40,42,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-18,20-24,38 and 42* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 09 January 2009 has been entered in full. Claims 1, 12-16, 20, 23-25, 28-31, 35, 37-38, and 42 are amended. Claims 27, 32, 41, 43, and 46-47 are cancelled.

Claims 1-26, 28-31, 33-40, 42, 44, 45 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objections to claims 1-16, 19, 24-35, 39-40, 42-45 as set forth at pages 2-3 of the previous Office Action (29 October 2008) are *withdrawn* in view of the amended and cancelled claims (09 January 2009).

2. The rejections of claims 6-8, 25-45 under 35 U.S.C. 112, second paragraph, as set forth at pages 3-4 of the previous Office Action (29 October 2008) are *withdrawn* in view of the amended and cancelled claims and Applicant's persuasive arguments (09 January 2009).

Claim Objections

3. Claim 11 is objected to because of the following informalities:

3a. In claim 11, line 2, the phrase "acid corresponds" should be amended to recite "acids correspond".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12-18, 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 12-18 and 20-24 are rejected as being indefinite because it is not clear **(1)** if the full-length BAFF-R glycoprotein of claim 1 already inherently comprises the amino acid sequences listed as (a)-(f), **(2)** if the full-length BAFF-R is further modified by the *addition or fusion* of the amino acid sequences listed as (a)-(f), or **(3)** if the extracellular domain of the full-length BAFF-R glycoprotein consists of the amino acids listed as (a)-(f).

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 38 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated host cell comprising a nucleic acid and a method for treating an autoimmune disorder characterized by an elevated BAFF level *does not reasonably provide enablement* for (1) a host cell comprising a nucleic acid or (2) a method for treating an immunological disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pages 4-10 of the previous Office Action (29 October 2008).

Applicant's arguments (09 January 2009), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) Regarding Examiner's interpretation of claims 23, 24, and 38 as reading upon host cells intended for gene therapy, at page 13 of the Response, Applicant indicates that these claims have been amended to recite "isolated".

Applicant's argument has been considered but is not found to be persuasive. Specifically, claim 38 has not been amended to recite "isolated host cell" and thus, still reads upon host cells intended for gene therapy. As discussed in the previous Office Action of 29 October 2009, the specification does not teach any methods or working examples that indicate a ΔBAFF-R nucleic acid is introduced and expressed in a cell for therapeutic purposes. The disclosure in the specification is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Also, undue experimentation would be required of the skilled artisan to introduce and express a ΔBAFF-R nucleic acid into the cell of an organism. Additionally, gene therapy is unpredictable and complex wherein one skilled in the art may not necessarily be able to introduce and express a ΔBAFF-R nucleic acid in the cell of an organism or be able to produce a ΔBAFF-R protein in that cell.

(ii) At page 15 of the Response of 09 January 2009, Applicant argues that claim 42 has been amended to recite a method for treating an autoimmune disease or a B cell cancer. Applicant asserts that the references cited by the Examiner explicitly recognize the rationale for using a BAFF antagonist to treat these indications. Applicant points out that Schneider et al. states that the BAFF system is a promising target of autoimmune diseases. Applicant also indicates that

Tangye et al. state that by targeting BAFF, "it should now be possible to improve treatment of antibody-mediated autoimmune diseases and B cell malignancies in a manner similar to the way anti-CD20 mAB (Rituximab) revolutionized therapy of RA and NHL". Applicant contends that the specification demonstrates the BAFF-R glycoproteins bind to BAFF (examples 3, 4, 9) and inhibit BAFF from binding to B cells and delivering a pro-survival signal (Examples 5, 7, 8). Applicant concludes that in light of Applicant's data showing that the BAFF-R glycoproteins are BAFF antagonists and the expectations in the art regarding the therapeutic applicability of BAFF antagonists as a class, the skilled artisan would expect that autoimmune diseases and B cell cancers could be treated by administering the disclosed BAFF-R glycoproteins.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, claim 42 still recites "a method for treating an immunological disorder comprising..." and was not amended to recite a method for treating an autoimmune disease or a B cell cancer. Thus, as discussed in the previous Office Action of 29 October 2008, the phrase "immunological disorder" has been broadly interpreted by the Examiner as encompassing any and all immunological diseases or disorders. Undue experimentation would be required of the skilled artisan to administer the BAFF-R glycoprotein to individuals with all possible immunological disorders and treat the disorder.

However, even if claim 42 had been amended to recite a method for treating an autoimmune disease or a B cell cancer, the amendment and Applicant's arguments still would not have been persuasive. Example 8 of the instant application (pages 40-43) only teaches that vBAFF-R(R3-49):Fc impairs B cell survival, resulting in a reduction of peripheral B cells and a reduction in the level of B cell surface markers, CD21 and CD23, *when administered in low*

doses (page 40, [0117]; page 42, Table 6; page 43, Table 7). This result is not observed when higher doses of vBAFF-R(R3-49):Fc are administered (see page 42, Table 6; page 43; Table 7). Furthermore, there are no methods or working examples to indicate that a BAFF-R glycoprotein or fusion protein treats any immunological disorder, autoimmune disease, or B cell cancer. A large quantity of experimentation would be required by the skilled artisan to determine whether the claimed BAFF-R glycoprotein and fusion protein treat any immunological disorder, autoimmune disease, or B cell cancer. Such experimentation is considered undue.

The Examiner acknowledges that the post-filing date reference of Schneider et al. (Immunol Lett 88(1):57-62, July 2003) states that the BAFF system is an important target for acting on the B cell arm of the immune system and that BAFF inhibitors could preserve some aspect B cell function (page 60, column 2, last paragraph). Schneider et al. continues to state that "[t]his rather selective way of manipulating the immune system should provide an additional tool to deal with complex autoimmune diseases such as rheumatoid arthritis, systemic lupus and possibly some types of lymphomas" (page 60, column 2, last paragraph; emphasis added by Examiner). Thus, it is clear that even after the instant invention was made, the relevant literature simply recognizes that BAFF inhibitors might be useful for complex autoimmune diseases. As discussed in the previous Office Action, Kalled et al. (Expert Opin Ther Targets 7(1): 115-123, 2003) and the post-filing date reference of Tangye et al. (Sem Immunol 18: 305-317, 2006) disclose that BAFF-R is a target for autoimmune diseases that have an elevated BAFF level (see pages 115, 117-120 of Kalled; pages 310-311 of Tangye et al.).

Hence, based upon the limited teachings of the instant specification and the relevant literature, the skilled artisan would not be able to predict that the BAFF-R glycoprotein or fusion

protein of the instant invention would be able to treat all possible immunological disorders or autoimmune diseases that are not characterized by elevated levels of BAFF. Furthermore, the limited guidance in the specification is not adequate, and is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. As was found in Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity. See also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation to introduce and express a ΔBAFF-R nucleic acid in a cell of an organism for therapy and treat all possible immunological disorders; the lack of direction/guidance presented in the specification regarding the same; the absence of working examples directed to same; the complex nature of the invention; the state of the prior art which establishes the unpredictability of transferring genes into an organism's cells, and the breadth of the claims which fail to recite any specific diseases, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
08 May 2009

/Bridget E Bunner/
Primary Examiner, Art Unit 1647